APPLICATION FOR
UNITED STATES PATENT

in the name of

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for

Pulse Sensors

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04644-088001

DATE OF DEPOSIT: May 1, 2001

EXPRESS MAIL NO.: EL224700820US

Pulse Sensors

TECHNICAL FIELD

This invention relates to pulse sensors and methods of using pulse sensors in conjunction with defibrillators.

BACKGROUND

The pulse is a very important parameter that is used to aid users of automated external defibrillators in determining whether or not to administer a defibrillation shock to and/or to perform cardiopulmonary resuscitation (CPR) on a victim who appears to be in cardiac arrest. Such a victim may actually be in need of cardiac resuscitation (including defibrillation and/or CPR), or may be suffering from a condition for which such treatment would be unsuitable, e.g., a stroke, seizure, diabetic coma, or heat exhaustion. It is very important to the safety of the victim that the presence or absence of a pulse be determined quickly and accurately. However, it is often difficult for trained medical personnel to take a victim's pulse accurately in the field during a crisis situation, and may be impossible for a minimally trained or untrained lay rescuer to do so. In many cases, it will take the person assisting the victim a considerable time (on the order of one minute or more) to find the victim's pulse. If a pulse is not found, the caregiver is left unsure as to whether the victim does not have a pulse, or whether the caregiver simply cannot find the victim's pulse.

Another parameter that is used in determining whether to administer a defibrillation shock is an ECG analysis of the victim's heart rhythm that is provided by the automated external defibrillator. Based on the ECG analysis, many automated defibrillators will provide the user with a message indicating whether a shock should be administered (i.e., whether or not ventricular fibrillation is present).

Generally, the ECG analysis systems in most commercially available automated external defibrillators display only two options to the user: "Shock Advised" or "No Shock Advised." When "Shock Advised" is output, this means that the patient is in ventricular fibrillation or wide complex ventricular tachycardia above 150 BPM, conditions which are effectively treated by defibrillation. When "No Shock Advised" is output, this means that the patient's heart rhythm is not treatable by defibrillation therapy.

If the message indicates that a shock is not appropriate, this does not necessarily mean that the victim is not in danger. There are two ECG rhythms, generally referred to as asystole and pulseless electrical activity, which should not be treated with defibrillation (and thus will trigger a message not to shock) but nonetheless are extremely serious in that they suggest that the patient's heart rhythm has deteriorated beyond fibrillation (i.e., the patient is close to death). These conditions are treated by administering cardiopulmonary resuscitation (CPR), in an effort to provide blood flow to the heart and vital organs in the hope that with improved blood flow and oxygenation, the heart muscle will recover from its near death state and possibly begin to fibrillate again, thus making defibrillation treatment a viable option.

Thus, when a "No Shock Advised" analysis is output, the caregiver does not know whether this result is caused by a normal heart rhythm, an abnormal but perfusing heart rhythm (i.e., the patient was never in cardiac arrest or the last shock treatment returned the patient's heart rhythm to normal), or a grossly abnormal (non-perfusing) ECG rhythm requiring CPR treatment. Because of this uncertainty, the normal medical protocol when "No Shock Advised" is output is to check the patient for a pulse and if no pulse is detected to start CPR. If a pulse is detected, then the patient's heart is effectively pumping blood and neither CPR nor defibrillation is warranted. If the victim does not have a pulse, CPR should be started immediately; if a pulse is present, then CPR should not be administered. Because CPR, even if properly administered, can result in broken ribs or other injury to the victim, it is undesirable to administer CPR if it is not actually necessary. Thus, it is again vitally important that an accurate determination of the presence or absence of a pulse be made by the caregiver.

A similar situation of uncertainty occurs after the third defibrillation shock is delivered in the three-shock protocol recommended by the American Heart Association. In this case, if the patient's fibrillation has not been "cured" after delivery of three shocks, the caregiver is instructed to perform CPR on the patient. Because automated external defibrillators generally do not perform an ECG analysis immediately after the third shock, the caregiver does not know whether the third shock provided effective treatment. Therefore, the caregiver must determine whether the patient has a pulse in order to determine whether CPR is needed or whether the patient is out of danger.

SUMMARY

The inventors have found that pulse sensors fabricated from piezoelectric polymer films, when used in conjunction with automated external defibrillator machines, enable users of such machines to make a quick and accurate determination of the appropriate treatment (defibrillation, CPR, or no cardiac-related treatment) for a victim who appears to be suffering from cardiac arrest. Such sensors provide an accurate determination of the presence or absence a victim's pulse, even under adverse conditions, thus significantly reducing the risk that an inappropriate and even dangerous treatment will be given erroneously to a victim. The accurate pulse determination thus provided relieves the uncertainty experienced by caregivers in the circumstances discussed above, and thus increases the likelihood of the patient receiving prompt, safe and effective treatment.

The inventors have also found that piezoelectric polymer pulse sensors can be used to determine whether CPR is necessary, in the event that an automated defibrillator indicates that it is not appropriate to shock a victim who appears to be suffering from cardiac arrest.

The invention also features methods of using piezoelectric polymer pulse sensors to measure the efficacy of CPR, when CPR is used in conjunction with or instead of defibrillation.

The piezoelectric sensors of the invention, when applied to areas of a human body where mechanical movement is present because of blood flow, will produce a significant electrical signal that is proportional to and representative of changes in blood flow activity. This will be the case whether the blood flow is due to normal or abnormal heartbeat action, or due to cardiopulmonary resuscitation action. The sensor will operate in either a flexural or a tension mode, and the produced electrical signal from the sensor may be utilized as either a voltage (high impedance) or a current (low impedance).

In one aspect, the invention features an automated defibrillator comprising defibrillator electrodes and a piezoelectric polymer pulse sensor.

Implementations may include one or more of the following features. The automated defibrillator further includes instrumentation for performing an ECG analysis. The automated defibrillator further includes instrumentation for analyzing a signal obtained from the pulse sensor. The pulse sensor is self-shielded. The automated defibrillator further includes a strap for attaching said pulse sensor to a patient's neck. The piezoelectric pulse

sensor is mounted on one of said defibrillator electrodes. The automated defibrillator further includes a display constructed to display information to a user. The automated defibrillator further includes instrumentation for converting the results of the ECG analysis and signal analysis into a message to be displayed to the user or provided as an auditory prompt.

In another aspect, the invention features a medical device including a piezoelectric polymer pulse sensor; and a strap constructed to allow the pulse sensor to be attached to a patient's neck.

Implementations may include one or more of the following features. The pulse sensor is self-shielded. The strap includes an elastic material. The device further includes a cable to connect the pulse sensor to instrumentation.

In a further aspect, the invention features a medical device including a piezoelectric polymer pulse sensor, and a foam pad having a first surface to which the pulse sensor is attached, and a second surface constructed to be attached to a patient.

In another aspect, the invention features a method of treating a patient showing signs of possible cardiac arrest including applying a piezoelectric pulse sensor to the patient; applying electrodes of a defibrillator to the patient; and using the pulse sensor to detect whether the patient has a pulse.

Implementations may include one or more of the following features. The method includes monitoring the pulse if present. The defibrillator has an ECG function and the method further includes using the ECG function of the defibrillator to monitor the patient's heart rhythm. The method further includes analyzing the pulse and heart rhythm to determine the appropriate treatment for the patient. The analyzing step includes determining whether the patient's pulse, if present, is correlated with the R-wave of the patient's heart rhythm. The analyzing step includes determining whether the ECG rhythm is treatable with defibrillation. The method further includes, if the determination is positive, delivering a shock to the patient using the defibrillator. The method further includes delivering a predetermined number of shocks to the patient, and then subsequently determining whether the patient's pulse, if present, is correlated with the R-wave of the patient's heart rhythm. The method further includes, if the subsequent determination is negative, administering CPR to the patient. The method further includes using the pulse sensor to determine the efficacy of the CPR treatment.

In a further aspect, the invention features a method of treating a patient showing signs of possible cardiac arrest comprising: (a) applying a piezoelectric pulse sensor to the patient; (b) using the pulse sensor to detect whether the patient has a pulse; and (c) using the pulse sensor to determine whether to apply electrodes of a defibrillator to the patient.

In another aspect, the invention features a method of treating a patient showing signs of possible cardiac arrest including (a) applying a piezoelectric pulse sensor to the patient; (b) using the pulse sensor to detect whether the patient has a pulse; and (c) using the pulse sensor to determine whether to perform CPR on the patient.

Other features and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

Fig. 1 is a flow diagram illustrating steps in a method according to one embodiment of the invention.

Fig. 2 is a flow diagram illustrating steps in a method according to an alternate embodiment of the invention.

Fig. 3 is a diagrammatic view of a pulse sensor in use on a patient.

Fig. 4 is an enlarged diagrammatic cross-sectional view of a pulse sensor according to one embodiment of the invention.

Figs. 4A and 4B are unfolded and folded top views of the sensor element shown in Fig. 4; Figs. 4C and 4D are unfolded and folded bottom views of the sensor element.

Fig. 5 is a schematic of the equivalent electrical circuit of the piezoelectric polymer film component of the pulse sensor.

Fig. 6 is a circuit diagram of a complete pulse sensor assembly.

Fig. 7 is an example of a data acquisition scan performed using the pulse sensor of Fig. 4.

Fig. 8 is a diagrammatic representation of a pulse sensor according to an alternate embodiment of the invention.

Fig. 9 is a diagrammatic representation of a sculpted sensor with enhanced sensitivity.

Fig. 10 is a side view of a piezoelectric polymer film sensor element with neutral plane inducer for optimized sensing of bending moments of the thickness member.

Fig. 11 is a cross sectional diagram of a piezoelectric polymer film pulse detector integrated into the fabrication of a defibrillator pad.

Fig. 12 is a cross sectional diagram of a piezoelectric polymer film pulse detector for use in a slightly concave body area such as that encountered in the area of the neck at the carotid artery.

Fig. 13 is a schematic representation of a piezoelectric polymer film sensor element with a transimpedance (current to voltage converter) amplifier.

Fig. 14 is a schematic representation of a piezoelectric polymer film sensor element with an integrating amplifier (charge amplifier).

Fig. 15 is a schematic representation of a piezoelectric polymer film sensor element with a voltage amplifier.

DETAILED DESCRIPTION

Figs. 1 and 2 show methods of using a pulse sensor and defibrillator to determine the appropriate treatment for a victim who appears to be suffering from cardiac arrest. Both methods utilize a pulse sensor, described in further detail below, and an automated defibrillator. The automated defibrillator includes (a) a pair of electrodes that are placed on the victim's chest, (b) instrumentation constructed to receive signals from the electrodes, monitor the victim's ECG based on the received signals, and deliver a shock to the electrodes, and (c) a display constructed to display information and recommendations to the caregiver. Suitable automated defibrillators are commercially available from Zoll Medical Corp., Burlington, MA, e.g., M-Series Automated External Defibrillators. The instrumentation also includes the capability of comparing the R-wave of the heart rhythm monitored by the ECG to the victim's pulse to determine whether the two signals are synchronized. Together, the pulse sensor and defibrillator constitute a treatment system for victims who appear to be suffering from cardiac arrest.

Fig. 1 illustrates a method according to a first embodiment of the invention. In this method, the pulse sensor and defibrillator are used to control the initiation of ECG analysis and to advise a caregiver whether it is appropriate to administer a shock and/or CPR.

Referring to Fig. 1, when a victim shows signs of cardiac arrest, e.g., fainting, a caregiver applies a pulse sensor and the electrodes of a defibrillator to the victim (100).

Generally, as shown in Fig. 3, the pulse sensor is applied by fastening an elastic strap 20 carrying the sensor element 22 around the victim's neck 24, so that the sensor element 22 is held in close contact with the victim's carotid artery by the elastic strap 20. The strap is fastened snugly but not tightly about the neck. Generally, to obtain an optimal signal the sensor should be placed on the left side of the neck orthogonal to and centered on the carotid artery. If desired, other locations on the patient's body where a pulse can normally be detected may be used instead of the neck. The neck is generally preferred since it is the measurement and sustenance of blood flow to the brain which is of ultimate importance and the carotid artery carrying this flow provides a strong signal if a pulse is present. The sensor element 22 is connected, e.g., by a coaxial cable, to instrumentation 26, which is preferably incorporated in the instrumentation of the defibrillator. The electrodes of the defibrillator are applied in a conventional manner.

Referring again to Fig. 1, the victim's pulse is detected and monitored by the pulse sensor, and the victim's heart rhythm is monitored by the ECG function of the defibrillator via the defibrillation pads. The instrumentation of the defibrillator determines whether the victim's pulse is correlated with the R-waves of the victim's heart rhythm (102). If the pulse and R-waves are synchronized, then a display on the defibrillator indicates to the caregiver that the victim does not appear to be in cardiac arrest, and that the victim should not be shocked or treated with CPR (104). In this case, the caregiver puts the victim in a "rescue" position, according to standard first aid protocol, and continues to monitor the victim's pulse and ECG (106) so as to observe if a change in synchronization, a loss of pulse signal or ventricular fibrillation should occur (108).

If the victim's pulse is or becomes unsynchronized with the R-waves, the defibrillator then performs an ECG analysis (110) to determine whether the victim's heart rhythm should be treated by administering an electrical shock, i.e., whether the victim is suffering from ventricular fibrillation or wide complex ventricular tachycardia (112).

If a shockable rhythm is detected, the display of the defibrillator advises the caregiver to administer a shock to the victim (114). The caregiver delivers a shock to the victim, and the defibrillator then performs another ECG analysis to determine whether a shockable rhythm is detected (110). As long as a shockable rhythm is detected, this process is repeated for three shocks (116). Once three shocks have been administered, the system checks again

to see whether the victim's pulse is synchronized with the R-waves (118). If synchronization is not detected, then the display advises the caregiver to administer CPR for a specified period of time (120) and then to discontinue CPR (122). After CPR is discontinued, the ECG analysis (110) and following steps are repeated. If synchronization is detected, then a display on the defibrillator indicates to the caregiver that the victim does not appear to be in cardiac arrest, and that the victim should not be shocked or treated with CPR (104), and treatment proceeds as discussed above with reference to steps 106-108.

If a shockable rhythm is not detected, this indicates that either the victim is not suffering from cardiac arrest or that the victim has a condition that is not treatable by defibrillation (124). The system then checks again to see whether the victim's pulse is synchronized with the R-waves (118), and treatment proceeds, based on the results, as discussed above.

Fig. 2 illustrates an alternative method, in which the pulse sensor is used only to advise the caregiver whether it is appropriate to administer CPR. In this method, the ECG analysis is used alone to advise the caregiver whether it is appropriate to administer a defibrillation shock. This method may be used in cases in which checking the patient's pulse prior to applying the defibrillator electrodes is deemed to be unnecessary, e.g., the protocol that is currently recommended by the American Heart Association for lay caregivers. The other steps of the method shown in Fig. 2 are as described above with reference to Fig. 1.

Preferably, the pulse sensor is a piezoelectric polymer sensor. Piezoelectric sensors are, in their simplest form, capacitive electromechanical transducers that generate electrical charge in proportion to applied stress. The primary purpose of these sensors in the present invention is to generate an electrical signal that is proportional to the force caused by blood flow (pulse) in the area of the carotid artery or other areas of the body where a pulse could be detected. The sensors of the invention are not mechanically clamped at their periphery, and are primarily sensitive to longitudinal stress as opposed to a sound pressure wave front. Although the sensor material is somewhat sensitive to stress applied normal to its thickness and width, the sensor is designed to be most sensitive to stresses applied normal to its length (or "machine direction").

As blood flows through the carotid artery, or other area (either by normal heart action or as a result of CPR), the artery expands and exerts a small amount of stress on the sensor,

which is in close contact with the exterior of the patient's neck, as discussed above. The stress induced in the sensor thus reflects changes in arterial blood flow.

As shown in Fig. 4, the sensor includes a piezoelectric polymer film 30, a common metalization layer 32 and a signal metalization layer 34. Because piezoelectric sensors are generally of very high impedance, electrical interference is often problematic. To minimize electrical interference at the sensor surface, the sensor may be fabricated in a folded (self-shielding) manner, as shown in Figs. 4, 4B and 4D, so that the common metalization layer 32 almost completely envelops the exterior of the sensor. The sensor is shown prior to folding in Figs. 4A and 4C (top and bottom views, respectively) in which the dashed line indicates the line about which the sensor is folded. The sensor is held in its folded position by a layer of compliant adhesive 36 (Fig. 4). This shielding technique, in conjunction with coaxial cable connections, greatly minimizes interference created by undesirable stray electrical fields.

A data acquisition scan performed using the pulse sensor of Fig. 4 is shown in Fig. 7. The voltage signal level is approximately 100 mv p-p with most of the energy being spectrally located at about 1.2 Hz, indicating a pulse rate of 72 beats/minute (bpm).

Suitable piezoelectric polymer films include polyvinylidine fluoride (PVDF) and co-polymers thereof. Such piezoelectric polymer films are commercially available, e.g., from Measurement Specialties, Inc. of Valley Forge, PA (e.g., Part No. 1-1004347-0). Preferably, the thickness of the polymer film is between about 0.001 and 0.005 inch.

A preferred sensor material is polarized piezoelectric polymer film sheet, about 28 micron (~.001 inch) thick with a silver conductor printed on both sides for a total thickness of about 40 microns (~.0015 inch). The sensor material may be approximately 5 inches in length and folded back upon itself with compliant adhesive, as shown in Fig. 4, to create a self-shielded sensor that is approximately 1.0 inch in width and 2.5 inches in length.

An electrical signal is produced (as measured between the 'signal' and the 'shield' electrodes) when any stress is applied (especially in the longitudinal axis) to the sensor. The circuit shown in Fig. 5 consists of a voltage source in series with a capacitor. This circuit is acceptable for visualization and modeling of sensor elements of this type as long as the frequency is below ultrasonic range.

The capacitance exhibited by these sensors is approximately 10nF and loss tangent is less than 0.02. Because the leakage is so low, it is generally necessary to eliminate long term buildup of charge (DC drift) on the electrodes due to triboelectric, pyroelectric or other phenomena especially when the sensor element is to be connected to a high (>10 meg ohm) impedance instrument. Eliminating this undesirable DC drift (charge buildup) is accomplished (at the expense of low frequency response) by placing a 'termination' resistor (10Meg ohm) across (in parallel with) the sensor, as shown in Fig. 6. The termination resistor allows charge to bleed off from the sensor thus eliminating long-term voltage drift. The loss of low frequency response does not generally pose a problem, as it is typically preferable to minimize low frequency (<1Hz) response so as to attenuate signals due to breathing or other slow artifacts.

Fig. 6 also shows the capacitance associated with the cable, which is used to connect the sensor to the instrumentation or other apparatus. The capacitance of the connecting cable appears in parallel with the capacitance of the sensor. This should not significantly impair the operation of the sensor as long as the cable capacitance is not appreciably large as compared to the capacitance of the sensor. If the sensor were operated in the 'current' mode (connected to a transimpedance amplifier, as shown in Fig. 13, or a charge amplifier, as shown in Fig. 14) the effect of the cable capacitance on the entire sensor system operation would be eliminated since there would be no appreciable voltage for the cable capacitance to charge to.

The sensor electronics shown in Figs. 13-15 may be integrated onto the sensor, or may be connected as a remote sensing instrument.

Other embodiments are within the scope of the following claims.

In alternative embodiments, a piezoelectric polymer sensor element 22' may be bonded to the surface of a compliant thickness member, e.g., a foam pad 50 as shown in Figs. 8 and 9, to form a sensor assembly. A coaxial cable and terminating resistor are affixed to the foam pad and electrically connected to the sensor element. An epoxy 48 is applied to the resistor/cable/sensor area for protection. This sensor is designed to be most sensitive to forces which are normal to the length of the sensor. If desired, a second foam pad (not shown) may be adhered over the resistor/cable/sensor area. The foam pad is preferably about 1 to 2 mm thick, more preferably about 1.5 mm.

As shown in Fig. 9, if desired the foam pad 50 may be contoured in regions 51 to enhance signal sensitivity by allowing more stress to be felt by the sensor element 22.

As shown in Fig. 10, the piezoelectric sensor may also be bonded to the surface of a neutral plane inducer 52, i.e., a compliant but non-stretchable member that converts any flexure in the assembly into a tensile or compressive motion normal to the sensor's length. Piezoelectric polymer sensors may be bonded to both opposing surfaces of a foam pad (not shown). Because any flexure in this assembly will cause tensile force in one sensor while simultaneously causing compressive force in the other sensor, the combined electrical signal will be differential in nature with advantages in increased sensitivity and improved common mode rejection of unwanted signals such as noise or pyroelectric response due to temperature transients.

As shown in Fig. 11, the sensor element 22 (shown in Fig. 4 and described above) and foam pad 50 may be bonded to a defibrillator electrode 53, so that the sensor element may be attached to the chest as part of the defibrillator electrode. The defibrillator electrode includes a pressure-sensitive adhesive 56 and a conductive hydrogel 58, as is well known in the defibrillator field.

As shown in Fig. 12, a stiff low mass object 54 may be bonded to the adhesive side of the foam pad to aid in making intimate contact with the carotid artery in cases where there are areas of depression in the neck surface.

The pulse sensor assembly may be used anywhere on the human body that a pulse can be detected, e.g., the neck, chest, wrist, arm or ankle. The unamplified voltage signal level output from the sensor should be in the approximate tenths of a volt range when properly affixed to an area of the body that exhibits a moderate pulse strength. The pulse sensor may be attached in a different manner, e.g., by a clip, as a patch, or using a suction device.

Small surface mount type electrical components such as operational amplifiers, resistors and capacitors may be integrated onto the sensor element and used to amplify the signal, provide noise immunity, mitigate the effects of cabling (parasitic capacitance and/or equivalent series resistance), filter certain frequencies, integrate the sensor electrical charge over time, double integrate the sensor electrical charge over time, scale and/or offset signal output, or otherwise accomplish signal conditioning functions for the electrical signals produced by the sensor element.

While automated defibrillators have been discussed above, the pulse sensor may be used in conjunction with a non-automated defibrillator. In this case the pulse sensor would be used by a trained caregiver as an aid in determining the proper course of treatment. The caregiver would observe displayed pulse and ECG signals and perform an independent analysis to determine the proper mode of treatment.

While the step of determining whether the patient's pulse signal and R-wave are synchronized is used in the methods described above, in many cases this step is not necessary. This step is a signal processing technique that is sometimes used to improve performance when one or both of the signals are contaminated with artifacts. Other suitable techniques include autocorrelation processing, matched filter processing, and other pattern recognition schemes. In some cases, e.g., if the signals are relatively uncontaminated, none of these techniques are required.